



TENNESSEE WILDLIFE RESOURCES AGENCY

ELLINGTON AGRICULTURAL CENTER
5107 EDMONDSON PIKE
NASHVILLE, TENNESSEE 37211

MEMORANDUM

TO: Tennessee Fish and Wildlife Commission

CC'd:

Nick Pinozzoto, President and CEO of National Deer Association; **Mike Butler**, CEO of Tennessee Wildlife Federation; **Dr. Krysten Schuler***, Wildlife Disease Ecologist and Assistant Research Professor at Cornell University; **Dr. Aaron Lehmkuhl***, Head of Pathology at USDA National Veterinary Services Laboratory; **Dr. Mark Ruder***, Co-Director of Southeastern Cooperative Wildlife Disease Study; **Dr. David Stallknecht***, Co-Director of Southeastern Cooperative Wildlife Disease Study; **Bryan Richards***, CWD Project Leader at USGS – National Wildlife Health Center; **Matt Dunfee**, Director of the Chronic Wasting Disease Alliance; **Dr. Collin Gillin***, Vice-Chair of AFWA Fish and Wildlife Health Committee, Lead author of AFWA's BMPs for CWD; **Gordon Batcheller**, President of The Wildlife Society; **Patrick Durkin**, Outdoors writer/editor;

DATE: September 6, 2022

FROM: James D. Kelly, Wildlife Data Scientist, Certified Wildlife Biologist®

SUBJECT: TWRA's Violation of Rule 1660-01-34

Dear Commissioners,

After waiting 10 months for transparency from the Director's office about the TWRA's mistakes regarding last year's CWD diagnostics, I now feel compelled to report the facts to the Commission so that it can understand TWRA's position with respect to managing CWD. Unfortunately, I can't provide all the details in this memo as it would take me weeks, if not months, to fully document all that has transpired in the past year. I would gladly develop a detailed report if given the permission to do so.

As you know, the TWRA has an obligation under Tennessee Regulations to maintain and publish a list of positive CWD counties and high risk CWD counties ([1660-01-34](#)). A county is positive for CWD upon confirmation that it has tested positive for CWD within the boundaries of the County. A county is high risk for CWD when there is a confirmed case of CWD within ten miles of the territorial boundaries of the county. TWRA violates this rule by falsely reporting counties as 'confirmed' positives.

Last year, the TWRA erroneously announced Henry, Weakley, Gibson, and Crockett counties as Positive CWD Counties and Carroll and Dyer as High Risk CWD Counties, accordingly. At the time the TWRA made this announcement, it did not know that the samples that led to announcing those counties as positive or high risk were actually *Not Detected* for CWD.

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At this time last year, the TWRA made a last-minute change to its protocol for how it would confirm suspect cases of CWD that would change the status of a county under 1660-01-34. It changed its protocol so that it no longer used the immunohistochemistry (IHC) test, or any other test for that matter, to confirm results from an ELISA suspect positive, hereafter referred to as *Suspect*. This decision arose from the following concepts that the TWRA was led to believe at the time:

- ELISA *Suspect's* are already confirmed because the diagnostics lab has to get multiple reactors for a given sample before reporting it as *Suspect*.
- ELISA is more sensitive than IHC (in other words, does a better job at detecting CWD than ELISA).
- ELISA can detect CWD at earlier stages of infection than IHC.
- ELISA *Suspect's* definitely have prions in them, and prions are the only thing that would yield an ELISA *Suspect*.
- Samples that are *Suspect* on ELISA and *Not Detected* on IHC are just false negatives on IHC.
- ELISA is better than IHC. IHC is antiquated, and policy just hasn't caught up to the "new science".
- Research proves all of the above.
- Everyone in the Wildlife Health community believes these concepts to be true too.

Given these assumptions and the fact that up until that point the TWRA had only ever had one county not be confirmed due to an ELISA *Suspect* failing confirmation with IHC, I reluctantly agreed to go along with recommending this new protocol. **However, the TWRA, including myself, would later learn that the concepts above were and are false.**

Unfortunately, this well-intended decision would prove to be confounded by another well-intended decision we made for the 2021-22 season – to make Kord Lab our primary diagnostics laboratory. To be clear, making Kord Lab our primary lab was not a mistake. However, that decision is what would ultimately enable the TWRA to realize that its change in confirmation protocol was a mistake.

By December 7, 2021, the TWRA had added four positive counties and two high risk counties using only 2,898 samples tested with ELISA, unconfirmed by IHC, and performed by Kord Lab. The results were suspicious; this was way too many counties being added, way too fast. By comparison, the TWRA sampled 18,654 the year prior (i.e., 2020-21 season) and added one positive county and one high risk county. At this point, sample volume from Kord Lab was 85% less than the total for the year prior but had already resulted in four times as many positive counties and twice as many high-risk counties.

Two days later the TWRA received results of samples using ELISA testing, unconfirmed by IHC, and from Kord Lab that defied logic. Kord Lab reported four *Suspect's* in three counties in East TN: Jefferson, Hawkins, and Claiborne. Not only are these counties not contiguous to any other CWD positive or high-

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risk counties, but these counties are not contiguous to each other. In fact, they are on the other side of the State of Tennessee.

All four of those ELISA *Suspect's* were *Not Detected* on IHC, an event that only happens around 6% - 8% of the time based on multiple peer-reviewed articles and based on our own data from other labs. As a result, we strongly suspected that there was lab error of some sort at Kord and that some of the counties that we had previously announced that season as positive or high risk in West TN were likely erroneous. To confirm, we retroactively tested on IHC the ELISA *Suspect's* from Kord Lab that changed the status of those counties announced earlier in the season. We also tested on IHC any other ELISA *Suspect's* we had received since announcing those counties that, if confirmed on IHC, would prevent us from having to rescind those counties. There were nine of these. All came back *Not Detected* on IHC.

So, an event that should only happen (using the more generous) 8% of the time (i.e., ELISA *Suspect*/IHC *Not Detected*), happened 13 times in a row! All from Kord Lab. The probability of that happening 13 times in a row under normal conditions (i.e., no confounding factors) can be calculated as

$\left(\frac{8}{100}\right)^{13} \times 100\% = 0.00000000000055\%$. In other words, it's impossible. This confirmed lab error, and it is when we should have been transparent with staff, TFWC, KY Dept of Fish and Wildlife, and the public that Henry, Weakley, Gibson, and Crockett counties were not positive for CWD and Dyer and Carroll counties were not high risk for CWD, accordingly. We knew about 12 of the 13 by January 26th, 2022. That is when I sent [this email](#).

At this point we were very cognizant of the fact that had we not changed our confirmation protocol at the beginning of the season, we would not have erroneously announced those counties. Those results would have simply been false positives on ELISA. After the second or third false positive from Kord Lab we could have let them know that their results had statistically significant outliers and asked them to do an internal audit to find out what the issue was. There wouldn't have been any public announcements involved. By comparison to the situation we are in now, it wouldn't have been a big deal at all.

Instead of attempting to correct the mistakes that had now become obvious, the TWRA very recently created [a newer, unprecedented CWD confirmation protocol](#) that, if blindly adopted, could prevent us from every knowing there was lab error contributing to the reporting of false positives. This even newer protocol not only has the effect of concealing false positives from last season, but it also makes the TWRA susceptible to erroneously announcing more counties. The [new protocol](#) also fully embraces the misconceptions listed above.

It is also resulting in plans to increase surveillance in Claiborne County based on a suspect ELISA that was *Not Detected* on IHC in December 2021. Region 4 (i.e., East TN) staff only very recently learned about this suspect positive. What they still don't know is that there were three other ELISA *Suspect's* from

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Region 4 that failed IHC. They were all in the same batch of samples and they were all mixed in with samples from Region 1 on the well plates when tested on ELISA by Kord Lab. TWRA is only sharing about one of the ELISA *Suspect*'s because it is looking at it through the retrofitted lens of this new protocol. After all, one ELISA *Suspect* in East TN doesn't sound nearly as suspicious as four ELISA *Suspect*'s in three discontinuous counties.

The new protocol also suggests that everything west of the Tennessee River is a "CWD-affected area", and therefore, doesn't need any further confirmation if *Suspect* on ELISA. That may seem plausible to a naïve audience when looking at the current, erroneous map, but I think you will agree it is unreasonable when considering the facts described herein.

Furthermore, the "additional evidence" approach to confirming an ELISA *Suspect* is not appropriate either because that is what convinced TWRA to erroneously announce Henry County as positive in the first place. It is a well-known fact that deer infected with CWD do not show clinical symptoms until late stages of infection – long after the disease would be detectable by ELISA or IHC. It is also a well-known fact that the clinical symptoms for CWD are consistent with a myriad of other deer diseases and conditions. Therefore, if an animal's clinical symptoms were truly due to infection from CWD, it would be a strong positive on ELISA and easily detected on IHC. The sample that led us to announcing Henry County was showing a clinical symptom of CWD (i.e., skinny) and it was a weak ELISA *Suspect*. We would later learn that this sample was also *Not Detected* on IHC. This new protocol sets us up to make the same mistake East of the Tennessee River.

Finally, this protocol has the potential to erroneously sound the alarms in states adjacent to TN counties with false positives.

The truth is that ELISA is a high-throughput screening that was never designed to be used without IHC confirmation. This is especially true for the National Animal Health Laboratory Network (NAHLN) protocol that Kord Lab adheres to. ELISA is not a confirmatory test. It enables us to quickly test a large volume of samples to see which ones need to be tested with the more expensive, more time-consuming, "gold-standard" IHC test. False negatives on IHC are not a concern, but false positives on ELISA can and do happen by nature of it being a high-throughput screening. The terminology around the ELISA protocol is important too. A suspect positive on ELISA isn't *confirmed* by multiple suspect positives. A sample tested with ELISA is a *Suspect* positive only when there have been multiple (i.e., at least 2 out of 3) *reactors* for that sample. A sample is not *Suspect* if there was only one reactor for that sample. In fact, our diagnostics laboratory wouldn't even report those to us under normal circumstances because there are extraneous factors besides prions that can cause a sample to react on ELISA. Therefore, the contention that TWRA met its obligation for confirmation under 1660-01-34 by simply

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using the reported result on ELISA is false. I encourage you to fact check with the subject matter experts copied on this memo with an asterisk (*) next to their name.

I have been a key player in the discovery of and response to CWD in TN, and that is putting it modestly. I was also asked to do an analysis of Kord Lab's raw data to try and determine the source of the error once it became obvious there was lab error from a statistical standpoint. I would be happy to share what that analysis found if given the opportunity to do so.

I have shared *ad nauseum* the irrefutable evidence described herein to my leadership. My repeated requests for transparency amongst relevant staff were all denied, but I was assured we would be transparent when the timing was better. Since December 2021 up until very recently, I had been reassured that we were going to make this right (i.e., be transparent and rescind the erroneously confirmed positives), and that I needed to keep the information confidential until then. The recent introduction of this new protocol and [announcement of Dyer County as a confirmed positive county](#) made it clear that TRWA does not intend to do that.

I hope that the information presented in this memo results in a thorough, independent investigation into the TWRA's decisions regarding CWD reporting and management. I trust that the facts uncovered during said investigation will confirm everything I have said here and will result in the following:

- the TWRA reinstating the IHC confirmation protocol TWRA had prior to the 2021-22 season,
- the TWRA IHC testing the Dyer County ELISA *Suspect*, and
- the TWRA publishing a corrected map of positive and high risk CWD counties using IHC confirmation protocol.

The fight against CWD depends upon accurately reporting where the disease is and is not, and I hope that by owning our mistakes and correcting the TWRA's protocol the TWRA can be a leader in this fight.

Please let me know how else I can help moving forward.

Humbly Yours,

James Kelly

[Resume/CV](#)

P.S. Here is a [video recording](#) of a recent meeting where Dr. Lehmkuhl confirms just about everything I say above regarding ELISA vs IHC.

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